

Notice of Allowability

Application No.

10/025,514

Examiner

Malgorzata A. Walicka

Applicant(s)

BARR ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 09/11/06.
2. ☒ The allowed claim(s) is/are 2, 4, 8, 16 -17, 26-42, 46-49.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 05/17/02
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

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Amendment and Response to Office Action filed Sept. 11, 2006 is acknowledged.

Claims 1, 3, 5, 7, 9-15, 18-25 and 43-45 have been previously cancelled. Claims 2, 4, 8, 16-17, 26-42 and 46-49 are pending. Claims 2, 4, 8, 16, 17, 36, 37 and 42 and 46-49 directed to the elected invention are the subject of this Office Action. In addition, claims 26-35 and 38-41 directed to a method of use of allowable product are under examination.

Detailed Office Action

1. Claim rejoinder

Claims 2 and 4 are directed to allowable products. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 38-39 and 40 have been rejoined in the Office action of March 9, 2006. As rejection of claim 2 has been overcome; see below, claims 26-35 directed to the process of making or using an allowable product of claim 2, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

2. Withdrawal of rejection under 35 U.S.C. 103

Claims 2, 8, claim 42 and dependent claims 46 and 49 were rejected 35 U.S.C. 103(a) as being unpatentable over Urwin P. et al, (*Enhanced transgenic plant resistance to nematodes by dual proteinase inhibitor constructs*, *Planta*, 1998, 204, 472-479, and WO 92/10575 document published 1992 in view of the article by Bingle L. et al., (*Secretory leucoprotease inhibitor: partnering alpha 1-proteinase inhibitor to combat pulmonary inflammation*, *Thorax*, Dec. 1996, vol. 51/12, pages 1273-1274). This rejection is now withdrawn, because Applicants' arguments

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are found persuasive. Particularly, in the REMARKS of Sept. 11, 2006, page 8, second paragraph Applicants emphasize:

“Finally, Bingle teaches away from combining the AAT to SLPI. Bingle teaches that the interaction between SLPI and NE [neutrophil elastase inhibited by SLPI and AAT] is reversible facilitating transfer of NE to AAT. Inactive NE-AAT complexes are cleared via the lymphatic vessels and blood, while SLPI is recycled. One skilled in the art would not want to combine SLPI to the AAT to result in inactive SLP-AAT-NE complexes.”

The same argument is repeated on page 9 of REMARKS, the last paragraph.

After reconsideration of the article by Bingle et al. the examiner indeed found that this is the case, because the teachings on page 1273 right column line 11 under the subtitle **Scientific basis** are as follows:

“SLPI is a hydrophobic cationic protein and, thus, will bind readily to NE and some of its substrates-for example, elastin/extracellular matrix. Unlike α_1 . PI [AAT in the instant application], it can inhibit elastin-bound NE. In addition, the interaction between SLPI and NE is reversible, facilitating transfer of NE to α_1 . PI. Inactive NE- α_1 . PI complexes are cleared via the lymphatic vessels and blood while SLPI is probably “recycled” to mop up remaining uninhibited NE.”

3. Examiner's amendment

Please amend claim 42 as follows.

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42. The fusion protein of claim 2, wherein said functionally active portion of alpha 1-antitrypsin [an] has elastase inhibitory activity and said functionally active portion of secretory leukocyte protease inhibitor has elastase inhibitory activity.

Authorization for this examiner's amendment was given in a telephone interview with Applicants' representative Leslie A. Mooi on Sep. 28, 2006.

4. Conclusion

Claims 2, 4, 9, 26-41 and 46-49 are allowed. The following is the examiner reason for allowance. Applicants disclosed a novel fusion protein consisting of alpha-1-antitrypsin protease inhibitor (AAT) and secretory leukocyte protease inhibitor (SLPI) which has twice as high inhibitory effect on neutrophil elastase, the substrate of both components, and antitrypsin activity which is half of the activity possessed by SLPI, the only component possessing this activity. The novel chimeric protease inhibitor has numerous potential therapeutic applications. The 103 rejection maintained in the Office Actions of August 24, 2005 and March 9, 2006 has been now withdrawn, in the light of Applicants arguments based on the reconsideration of the teaching of the prior art; see above.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

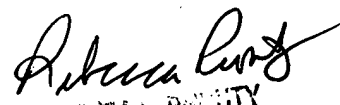
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.
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Patent Examiner


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